

Extrapolation: which is the patient perspective ?

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“ A STRONG PATIENTS' VOICE TO
DRIVE BETTER HEALTH IN EUROPE ”

The European Patients' Forum



- We are a **non-governmental umbrella organisation** set up in 2003
- We represent:
 - ✓ 63 pan-European and national patient organisations active in the field of European public health and health advocacy
 - ✓ 150 million patients with chronic conditions across the EU
- **VISION:** All patients with **chronic** and/or **lifelong conditions** in the EU have access to **high quality, patient-centred equitable health and social care.**
- **MISSION:** to ensure that the **patients' community drives** policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens in the EU.

Independent Inclusive Equitable
Empowering Patients Holistic Transparent
Patient-Centred Non-discriminatory Consultative

- Is there a patient's perspective about extrapolation ?
- Is this perspective unique ?
- Can this perspective be easily summarized ?
- Is there a “wider context” to be considered ?

The European Medicines Agency has been engaging in dialogue with European patients and consumers since it was founded in 1995.

As users of the medicines that the Agency evaluates, patients and consumers are key stakeholders in the Agency's work and have specific knowledge and expertise to offer.

The Agency is committed to maintaining a strong working relationship with these groups

Is there a unique patient perspective ?

Up to now:

- Patients' groups have not developed a unique position capable to summarize the different positions within the patient community;
- Tension between:
 - Fast access and safety
 - Guarantees of standardized procedures vs fast lanes
 - Adults // Paediatric Population
 - Different conditions = different priorities (Chronic vs Acute)

So far...

- There is not a unique position coming from the patient community, although different patients' groups may have developed their own view, based on their specific necessities, priorities and point of views.

This can be explained

- Through an analysis of the different perspectives
 - E.g. Age Groups, drug classes, type of condition to be treated

An example

- It may be wrong to think that extrapolation may found an easier reception when referred to its use in the adult population

- The respondents were explained that the biosimilar of Remicade[®] was approved for the treatment of IBD by extrapolating data from rheumatoid arthritis and asked how they felt about this.

- 30.3% of the respondents would prefer testing for IBD first (30.8% of respondents with CD, 29.4% of respondents with UC) and 24.3% are waiting for more IBD-specific data before accepting to receive a biosimilar for either Crohn's disease or ulcerative colitis (26.3% of respondents with CD, 21.0% of respondents with UC).
- Only 3.4% of the respondents would trust the decisions made by regulatory agencies and would not wait for IBD-specific data.

- 27.2% of the respondents would trust their treating physician to make the decision to use biosimilars in their treatment also in terms of extrapolation
- 0.8% would trust their pharmacist to make the decision to use biosimilars in their treatment.
- **13.1% of the respondents thought extrapolation makes sense.**

- These data refers to a specific class of drugs (Biosimilar – anti-TNFalfa) in a specific patient group (IBD) with a chronic condition
- Still this shows how reluctant the patient population is towards a concept that is:
 - Technical
 - Not easy to be understood without a proper background
 - When there is no specific “urgence” in getting the treatment (here they could get access to the bio-originals in most of the cases)

- The situation is more complicated when we refer to paediatric patients that are, for example, in a life-threatening condition
- The debate within the patient community is far to be closed but still there is the clear understanding that would be necessary to operate distinctions and consider specific necessities.

And also

- The debate may benefit (or in any case be influenced) by the outcomes of the ADAPTSmart initiative.

- Safety first
- But the concept of safety may be “adapted” to different specific cases (e.g. life-thr.)
- Ethic is a priority
- But above all is the patient, as human being, that always comes first

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